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ATTORNEY'S DOCKET NO: **H0535/7009/ERG**  
IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

GRAU 1617  
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Applicant: Howard Green, et al.  
Serial No: 09/359,920  
Filed: July 22, 1999  
For: TRANSGLUTAMINASE LINKAGE OF AGENTS TO TISSUE  
Examiner: Not assigned  
Art Unit: 1617

CERTIFICATE OF MAILING UNDER 37 C.F.R. §1.8(a)

The undersigned hereby certifies that this document is being placed in the United States mail with first-class postage attached, addressed to Assistant Commissioner for Patents, Washington, D.C. 20231, on the 6th day of October, 1999.

Maryanne Trevisan

Assistant Commissioner for Patents  
Washington, D.C. 20231

TRANSMITTAL

Sir:

Transmitted herewith are the following documents:

- \* Statement Filed Pursuant to the Duty of Disclosure Under 37 CFR §§1.56, 1.97 AND 1.98
- \* PTO 1449 Form (Modified) and Copy of Cited References
- \* Certificate of Mailing
- \* Return Postcard

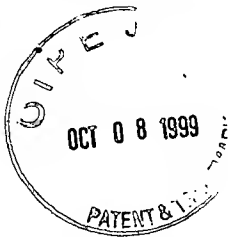
If the enclosed papers are considered incomplete, the Mail Room and/or the Application Branch is respectfully requested to contact the undersigned at (617)720-3500, Boston, Massachusetts.

If any fee is required, please charge to the account of the undersigned, Deposit Account No. 23/2825. A duplicate of this sheet is enclosed.

Respectfully submitted,

Edward R. Gates, Registration No. 31,616  
Wolf, Greenfield & Sacks, P.C.  
600 Atlantic Avenue  
Boston, MA 02210  
Tel. (617)720-3500

Docket No. **H0535/7009/ERG**  
Dated: October 6, 1999  
XNDD



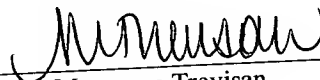
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Maryanne Trevisan

Assistant Commissioner for Patents  
Washington, D.C. 20231

STATEMENT FILED PURSUANT TO THE DUTY OF  
DISCLOSURE UNDER 37 CFR §§1.56, 1.97 AND 1.98

Sir:

Pursuant to the duty of disclosure under 37 C.F.R. §§1.56, 1.97 and 1.98, the Applicant requests consideration of this Information Disclosure Statement.

**PART I: Compliance with 37 C.F.R. §1.97**

This Information Disclosure Statement has been filed before the mailing date of a first Office Action on the merits in the above-identified case. No fee or certification is required.

**PART II - Information Cited**

The Applicant hereby makes of record in the above-identified application the information listed on the attached form PTO-1449 (modified). The order of presentation of the references should not be construed as an indication of the importance of the references.

The Applicant hereby makes the following additional information of record in the above-identified application:



**PART III - Explanation of Non-English Language References**  
**and Remarks Concerning Other Information Cited**

The following is a concise explanation of the relevance of each non-English language reference listed on the attached form PTO-1449.

**French Patent Publications**

EP 0285 474 "Skin Equivalent" was identified by the European Patent Examining Authority as an "X" reference with respect to claims 1 and 2 in PCT publication no. WO 94/18945. An English language translation of those portions which are relevant to the patentability of the claimed invention is attached hereto. Also enclosed is Australian patent publication AU-A-13742 (in English) which corresponds to EP 0285 474.

EP 0511 116 "Antigens Recognized by Antibodies Found in Patient with Rheumatoid Arthritis, their Preparations and their Applications," was identified by the European Patent Examining Authority as an "X" reference with respect to PCT claims 26-30. Applicants bring to the Examiner's attention that these claims were directed to "modified corneocyte proteins or polypeptide fragments." An English language translation of those portions which are relevant to the patentability of the claimed invention is attached hereto.

**Japanese Patent Publications**

English language translations of portions of the Japanese patent applications are attached to the Japanese patent applications.

JP Application No. TOKU KAI HEI 5-56785 describes the nucleotide sequence of DNA encoding a human epidermis transglutaminase.

JP Application No. HEI 2-204407 describes hair cosmetic formulations containing transglutaminase extracted from guinea pig liver and hydrophilic polyalcohols.

JP Application No. HEI 3-38511 describes an ointment which contains transglutaminase that is obtained from the livers of animals.

JP Application No. SHOU 61-172807 describes cosmetic formulations containing proteins that have been crosslinked in solution by transglutaminase.

**PART IV: Remarks**

A copy of each of the above-identified information is enclosed unless otherwise indicated on the attached form PTO-1449 (modified). It is respectfully requested that:

1. The Examiner consider completely the cited information, along with any other information, in reaching a determination concerning the patentability of the present claims;
2. The enclosed form PTO-1449 be signed by the Examiner to evidence that the cited information has been fully considered by the Patent and Trademark Office during the examination of this application;
3. The citations for the information be printed on any patent which issues from this application.

By submitting this Information Disclosure Statement, the Applicant makes no representation that a search has been performed, of the extent of any search performed, or that more relevant information does not exist.


By submitting this Information Disclosure Statement, the Applicant makes no representation that the information cited in the Statement is, or is considered to be, material to patentability as defined in 37 C.F.R. §1.56(b).

By submitting this Information Disclosure Statement, the Applicant makes no representation that the information cited in the Statement is, or is considered to be, in fact, prior art as defined by 35 U.S.C. §102.

Notwithstanding any statements by the Applicant, the Examiner is urged to form his own conclusion regarding the relevance of the cited information.

An early and favorable action is hereby requested.

Respectfully submitted,

  
Edward R. Gates, Registration No. 31,616  
Wolf, Greenfield & Sacks, P.C.  
600 Atlantic Avenue  
Boston, MA 02210  
Tel. (617)720-3500

Docket No. **H0535/7009/ERG**  
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